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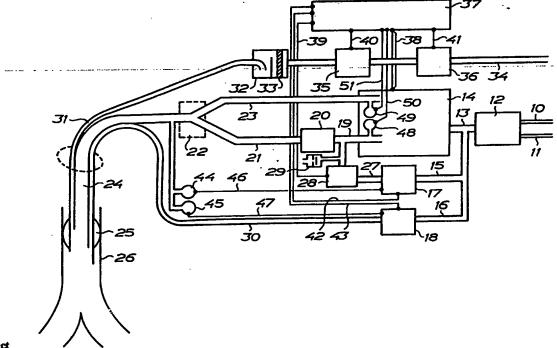
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(57) Abstract

Method and device for reduction of rebreathing of gas from the dead space, wherein during at least the final phase of the expiration, a flow of used breathing gas is evacuated through a gas conduit (31) which is inserted into the airway.

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METHOD AND DEVICE FOR REDUCTION OF REBREATHING OF GAS FROM DEAD SPACE

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The present invention relates to a method for reduction of rebreathing of gas from dead space and a device for practising the method. Dead space means the volume of used gas, which during the expiration has filled 15 the airways and is brought back to the alveolus at the following inspiration.

Several diseases result in difficulties or makes it impossible for the patient to achieve sufficient ventilation for adequate gas exchange of the alveolar space in the lungs. This results in the blood, which leaves the lungs, not having appropriate content of oxygen and carbon dioxide which often is referred to as respiratory insufficiency. Lack of oxygen can mostly be rectified by supplying to the patient breathing gas having a higher 25 oxygen content than that present in air, but when it comes to the carbon dioxide a positive effect cannot be achieved in a corresponding way. At serious respiratory insufficiency, respiratory treatment is applied to ensure the patient a sufficient alveolar ventilation. However, if the function of the lungs is seriously disturbed respiratory treatment can result in the pressure in the airway during injection of the breathing volume being very high, and it can then be a risk that the airway and the lung tissue are further damaged, a phenomenon often called barotrauma. In order to reduce the requirements of ventilation drastic actions are taken such as narcosis and muscle relaxation, reduction of the body temperature and extracorporeal elimination of carbon dioxide, but such

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measurements are extremely resource demanding and of limited medical utility.

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Positive pressures in the airway also result in other disadvantages except barotrauma: at circulation disturbances the circulation is often retarded in a detrimental way by positive intrapulmonal pressures. In such cases it is important to try to reduce the positive pressure and a method for achieving this is to decrease the volumes by which a patient is ventilated in a respirator.

A wellknown principle for treatment of respiratory insufficiency is to decrease the dead space, and this can be achieved by the patient being tracheotomied, which means that on the throat a ventilation aperture is made which connects the trachea with the outer space, but it is obvious that this measurement is connected with great disadvantages.

Another previously known principle for treatment of respiratory insufficiency consists in a certain amount of breathing gas being supplied during the respiratory treatment through a special gas tube to a point in the airway during the latter part of the expiration, the supplied gas volume displacing used breathing gas from the airway above the mentioned inlet point and the dead space then being decreased. This principle called airway flushing is useful but has certain limitations and even in some cases certain disadvantages. Thus, the extra gas supply gives some increase of the airway pressure, which at severe circulation insufficiency can be injurious. Principally at obstructive airway disease an abnormal high flow of gas from the alveolus occurs during the entire expiration. Then, if it is attempted to free the airway from used gas by means of airway flushing, the positive effect is partly lost due to the fact that the continuous flow of gas from the alveolus tends to fill again the airway with used gas. It is true that a large dilution of the gas flow from the

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alveolus can be achieved by flushing with a high flow, but then other disadvantages arise, for example further increased airway pressure. Another limitation of the previously known methods and devices for airway flushing is that they require a respirator and, therefore, cannot be used by patients that are not connected to a respirator.

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The object of the invention is to eliminate or at least considerably reduce the above-mentioned disadvantages of the known methods for reduction of rebreathing of gas from the dead space by the method according to the invention having obtained the characterizing features of claim 1.

For practising the method the device defined in claim 12 is suggested according to the invention.

For further explanation of the invention, the method according to the invention will be described with reference to the accompanying drawings, in which

FIG 1 is a diagram showing an embodiment of the device according to the invention for use in connection with respiratory treatment, and

FIG 2 is a diagram showing an embodiment of the device according to the invention for use at spontaneous breathing.

tubes for supply of breathing gases under overpressure, are shown, namely a conduit 10 for supply of, for example, air, and a conduit 11 for supply of, for example, oxygen. The conduits are connected to a gas mixer 12 for mixing the gases in desired, adjustable proportions, and from the gas mixer a conduit 13 leads to a respirator 14 which is assumed herein to be a respirator of the type ServoVentilator 900C from Siemens Elema AB, Solna. The conduit 13 is also connected through branch conduits 15 and 16 to two electrically controlled valve systems 17 and 18, respectively, comprising a plurality of microvalves of the

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type LIF LF AA 1200118H from The Lee Company, Westbrook, Connecticut, USA, which are connected in parallell and are normally closed. The respirator 14 has an outlet conduit 19 for inspiration gas with a damper and heater 20 and from this an inspiration hose 21 leads to one leg of a Ytube 22, the other leg of which is connected to the respirator through an expiration hose 23. The Ytube connects the inspiration and expiration hoses with a tracheal tube 24 which is provided with an inflatable sleeve 25 and is intended to be inserted into the patient's trachea which is shown at 26. The tracheal tube can be replaced by a tracheal cannula for connection of the respirator to the patient's airway. The valve system 17 is connected by a conduit 27 via a flowmeter 28 to the outlet tube 19. The conduit 27 is provided with a mechanic non-return valve 29 which constitutes a safety valve for supply of external air into the inspiration hose 21 if a underpressure should arise in this hose, which corresponds to approximately 5 cm water column. The valve system 18 is connected to a conduit 30 which opens close to the opening of the tracheal tube 24 and may consist of a thin catheter, which is situated inside the tracheal tube or can comprise an intramural cavity in the tracheal tube as in the Hi Lo Jet Tracheal Tube from Mallincrodt.

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An additional conduit 31 is provided in the same way as the conduit 30 and also has its opening close to the opening of the tracheal tube 24, and this conduit is connected through a trap 32 for secretion and a bacteria proof filter 33, built together to one unit, to a conduit 34, which is connected with a vacuum source, not shown herein, which can consist of a central evacuation plant or a vacuum pump. In the conduit 34 there is provided a flow meter 35 and a flow regulator 36, the latter being substantially of the same type as the valves controlling

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the inspiration and expiration flows of the respirator of the make mentioned herein.

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The described device comprises an electronic control unit 37 which may be of the type INTEL and includes among other things a micro processor and an analogue/digital converter. Through a main conduit 38 the converter is connected to the respirator 14 in order to receive signals therefrom, which indicate respiration phase, flows and pressures in the inspiration and expiration hoses 19, 21 and 23 respectively. The flowmeters 28 and 35 are also connected to the control unit through conduits 39 and 40, respectively, in order to supply to the control unit signals which represent the flows in the conduit 27 and the conduit 34, respectively, while a conduit 41 leads from the control unit to the flow regulator 36 and conduits 42 and 43 lead from the control unit to the valve system 17 and 18, respectively, for the supply of electric signals to these units from the control unit when the micro valves are to be opened. The valve systems 17 and 18 furthermore are connected each to one pressure sensor 44 and 45, respectively, through a conduit 46 and 47 respectively.

The respirator 14 comprises pressure sensors 48 and 49 in the inspiration conduit 19, 21 and the expiration conduit 23, respectively, which are connected to an automatic monitoring system in the respirator to interrupt the expiration at an unsuitable underpressure, for example -2 cm water column, in the expiration circuit and to interrupt the inspiration if an unsuitable high overpressure arises, and these pressure sensors are also connected to the control unit 37 through conduits 50 and 51, respectively.

By means of the described device, the method of the invention is practised in the following way:

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The respirator 14 operates in the conventional way, wherein gas is flowing to the patient's breathing system during the inspiration phase through the conduit 19 via the damper and the heater 20, and through the inspiration hose 21, the branch piece 22 and the tracheal tube 24, while during the expiration phase used gas is flowing through the tracheal tube and the expiration hose 23. In accordance with known principles, parts of the dead space can be flushed during the latter part of the expiration by one or more valves in the valve system 18 being opened by a signal from the control unit 37 via the conduit 43 and allow a constant or pulsating air stream through the gas conduit 30 for the ejection of an airjet close to the opening of the tracheal tube 24. Initially, the gas stream through the expiration hose 23 consists of used gas, but to the extent that used gas does not continue to stream from the lungs, parts of the patient's airways as well as the tracheal tube 24, and the Y-piece 22 will be filled with fresh gas from the gas conduit 30, the flushing effectivity thus being reduced.

This disadvantage is eliminated by providing in the control unit a comparison of the existing expiration flow with a flow programmed in this unit, in order that when the decreasing expiration flow sinks below a predetermined value, a signal will be supplied from the control unit through the conduit 41 to the flow regulator 36, which then will open to such extent that a predetermined flow which is programmed into the control unit will be evacuated from the patient's breathing system through the conduit 31, the separator 33 and the flow meter 35 through the conduit 34, connected to the suction source. This flow should preferably be chosen such that it is of the same order as the expiration flow which initiates the above described function. Thus, the flow from the patient's breathing system during the latter part of the expiration phase will

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be evacuated through the conduit 31, and the corresponding flow through the tracheal tube will cease.

At the same time as the described evacuation is initiated, a signal is supplied from the control unit through the conduit 42 to the valve system 17 in order that 5 said system during the expiration phase, will allow a predetermined flow through the conduit 27 via the flowmeter 28 to the outlet conduit 19 of the respirator 14 and via the damper and the heater 20 to the inspiration hose 21. When the flow of exhaled gas through the trachea 26 during 10 the continuing expiration phase decreases further in the last part of the expiration phase, said flow will fall below the flow which is being evacuated through the conduit 31, which results in a flow from the inspiration hose 21 through the Y-piece 22 and the tracheal tube 24. Fresh 15 heated and moistured gas thus will be supplied to the breathing circuit down to the lower end of the tracheal tube 24 during the last part of the expiration phase. To the extent that the flow of gas thus supplied to the breathing circuit is not considered to be sufficient to 20 flush all of the breathing circuit down to the lower end of the tracheal tube, the flow which is evacuated through the conduit 31 and the flow which is supplied through the conduit 27 via the valve system 17, can be increased to a suitable extent. It has been found that it is suitable to 25 control these two flows in such a way that the flow through the conduit 27 is slightly higher than the flow through the conduit 31, since this provides the advantage that the flow through the expiration hose 23 will be affected to a small extent only. The order of said latter flow is of importance 30 i.a for those monitoring systems which are included in the device in order to check that the patient undergoes sufficient ventilation and the function thereof being described further below. However, at the same time a certain flow is also achieved, which flushes the two legs 35

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of the Y-piece 22 and prevents rebreathing, via turbulence, of gas, contained in the expiration leg of the Y-piece. Furthermore, the advantage is gained that an end-respiratorical pressure which is adjusted on the respirator 14, will be more easily maintained in the presence of smaller leakage, which may occur mainly in the connection between the tracheal tube 24 and trachea 26 at the sleeve 25.

By practice of the method according to the invention in the device, described with reference to FIG 1, fresh gas 10 will be brought to fill the airway down to the tip of the tracheal tube 24 during the expiration phase under control by means of the valve system 17 in order to flush the dead space. Further flushing is achieved by the gas jet, which is supplied through the conduit 30 under control by means 15 of the valve system 18, and the gas jet, which in this way is supplied at the opening of the conduit 30 in the lower end of the tracheal tube, will reach down into trachea and the closest generations of airways which then can be 20 flushed. Then preferably the gas flow which is evacuated via the conduit 31 shall be controlled by means of the regulator 36 in such a way that the order thereof corresponds substantially to the sum of the flows which are supplied through the valve systems 17 and 18. The adjustment is controlled by means of the control unit 37. 25

In order that unsuitably high airway pressures will not arise in the airway at incorrect handling of the device according to FIG 1 or at malfunction of this device, the device has several safety systems. The two pressure sensors in the respirator 14 were mentioned above, which are connected to the control unit 37 and interrupt the expiration when an unsuitably high overpressure arises due to more gas being evacuated through the conduit 31 than is supplied by the patient's expiration, and by the valve systems 17 and 18, the valve systems 17 and 18 and the

flow-regulator 36 being brought to close by signals from
the control unit 37, which are initiated by signals from
the pressure sensors 48 and 49 through the conduits 50 and
51. If an underpressure should arise as a consequence of an
unsuitably adjusted respirator 14 or malfunction thereof,
there is a safety function built into the control unit 37,
the valve systems 17 and 18 and the flow regulator 36 being
closed, in dependence of the signals from the pressure
sensors 48 and 49 via the conduits 50 and 51 to the control
unit 37, if the pressure sensors indicate a value
corresponding to -4 cm water column. The mechanical valve
29 mentioned above starts to function and opens at an
underpressure of -5 cm water column, if both pressure
sensors 48 and 49 should fail or a fault should arise in
the control unit 37.

The pressure sensors 44 and 45 which are connected to the valve system 17 and the valve system 18, respectively, through the conduits 46 and 47 bring said valve systems to close if the pressure in the tracheal tube 24 should exceed a preadjusted value for the related valve system. This safety function should be such that it is necessary to reset manually for the valve system to open again.

The embodiment of the device according to the invention, which is shown in FIG 2 is intended to be used by a patient during spontaneous breathing. In this case, a catheter 52 of subcutaneous type is connected to the trachea 26, but instead a catheter could be inserted through the natural airway and could have the opening thereof in an optional location in the airway, for example in nasopharynx. To the catheter a two way valve 53 is connected, by means of which a pressure sensor 54 of the type which is used for measuring pressures within body cavities, can be connected to measure either the athmospheric pressure or the pressure in the catheter. The catheter is connected to two conduits 57 and 58 via an

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artificial nose 55, and a branch piece 56, the conduit 57 leading to an evacuation system 59, and the tube 58 leading to a system 60 for gas supply. The artificial nose is constructed according to previously known principles and comprises a porous hygroscopic material which stores heat and moisture when warm and moist expiration gas is passing through the artificial nose to the evacuation system 59, in order to return heat and moisture to the inhaled gas during the inspiration.

10 Each system 59 and 60, respectively, comprises a pressure sensor 61 and 62, respectively, of the type which is included in the above-mentioned respirator of type ServoVentilator 900C, and a flow meter 63 and 64, respectively, also of the same type as in the ServoVentilator 900C. Furthermore, each system 59 and 60, 15 respectively, includes a plurality of microvalves connected in parallel of the type LIF LF AA 1200118H from The Lee Company, which have been indicated by a valve symbol 65 and 66, respectively. The evacuation system 59 is connected to a conduit 67 through the valves 65 , said conduit leading 20 to a source for underpressure, not shown in FIG 2, which can comprise, for example, a central plant for gas evacuation or an evacuation pump for gases, while the system for gas supply is connected via the valves 66 to a 25 conduit 68 which extends from a source for breathing gas at overpressure, not shown in FIG 2.

The pressure sensors 61 and 62 are connected through conduits 69 and 70, respectively, to an electronic control unit 71, comprising i.a. an analogue/digital converter and a micro processor. The control unit is also connected through conduits 72 and 73, respectively, to the two flow sensors 63 and 64. Through the conduits 69, 70, 72 and 73 the control unit receives signals indicating pressure and flow in the conduits 57 and 58. The control unit is also connected to the valves 65 and 66, respectively, through

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conduits 74 and 75 to supply signals through these conduits, by which a suitable number of the normally closed valves are adjusted to open position. A conduit 76 is provided from the pressure sensor 54 to the control unit 71 to supply a pressure signal to the control unit which has a conduit 77 to the two-way valve 53 for switching such valve between the two adjusted positions thereof, the athmosphere and the catheter, respectively.

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Also a conduit 79 is connected to the conduit 58, upstreams of the flow-meter 64 through a valve system, indicated in FIG 2 by a valve symbol 78, of the same type as the valve systems 65 and 66, said conduit 79 being connected to a pressure regulator 80 to a source of oxygen or another gas. The normally closed valves 78 are connected through a conduit 81 to the control unit 71 in order to open a suitable number of valves on signal from the control unit.

The device according to FIG 2 operates according to routines which shall be programmed into the control unit 71, according to the example given below.

In an initial phase which according to the programme, is repeated at suitable intervals, the pressure sensor 54 will be connected to the athmosphere by an impuls supplied via the conduit 77 from the control unit 71 switching the two way valve 53. During the period which follows, the control unit 71 will read the signal from the pressure sensor 54, which corresponds to athmospheric pressure. Then, the two way valve 53 will be reset, so that the pressure sensor 54 will be connected to the airway through the catheter 52.

In a second phase the micro processor, forming part of the control unit 71, reads the signals from all three pressure sensors 54, 61 and 62 during a period corresponding to a number of breathes. The pressure signals are then compared with each other by linear regression. To

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the extent that the three signals do not show congruity, a fault indication will be given and further functions will be inhibited until the fault has been repaired and manual restart of the system has been made. Normally, the numerical constants which admit direct comparison of the measured pressure signals are stored in the micro processor.

In a third phase the pressure variation read during the second phase, will be analyzed in order to identify the 10 beginning and the end of the inspirations and expirations which have been registered. The lowest pressure measured which is found to be subathmospheric, is identified as an inspiration. The beginning of this inspiration will be searched and identified as the zero passage of the pressure 15 which precedes the lowest pressure previously found. If no zero passage is found during the read period, the beginning of the inspiration is left unidentified. Search for additional pressure minima and preceding zero passages thereof is made for identification of additional 20 inspirations and their beginning through the entire period which has been read during the second phase. Suitable filters and "eye-closing" periods are used to eliminate double identification of an inspiration. In the next moment of phase three pressure maxima between two following 25 inspirations are searched for. It is controlled that the pressure maxima are above the athmospheric pressure and then the maxima are identified as expirations. The beginning of every expiration is identified as the zero passage of the pressure signal which preceds each pressure maximum. The duration of the inspiration and the expiration 30 is tabulated in the micro processor together with respective pressure minima and pressure maxima. The process of a typical inspiration and expiration is determined as the final result of the process during phase three, and the typical pressure variation in diagrammatic form as well as 35

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numerical information, comprising above all the duration of different phases of the breathing cycle is presented on a picture screen.

During a fourth phase the registered variation is studied by a therapist, who is assumed to be a doctor or a breathing therapist. This person determines the volumes to be evacuated during the breathing cycle through the conduit 57, and the phase of the breathing cycle during which this is to be made. Furthermore, the therapist determines the volumes to be supplied through the conduit 58 and the phase of the breathing cycle during which this is to be made.

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The therapist also adjusts the highest levels concerning underpressure in the catheter 52 during the evacuation phase, and the highest values concerning overpressure in the catheter during gas supply. Limits concerning deviations from the typical breathing pattern, which is studied during phase three, are also determined.

> During a fifth phase which is a therapeutic phase, the device is brought to function in accordance with the principles of the invention and according to the routine established during phase four. During the total therapeutic phase the control unit continuously reads pressure values from the three pressure sensors 54, 61 and 62 as well as flow values from the flowmeters 63 and 64. The digital values are stored in a circle buffer in the memory of the micro processor, said circle buffer comprising a period of time which covers several breathing cycles. A subatmospheric pressure minimum is searched for and identified as an inspiration. Then, a superatmospheric pressure maximum is searched for, defining an expiration. When this has been found, the computer searchs the beginning of the actual expiration which is identified as the nearest preceding zero passage of the pressure and is found in the circle buffer. The processor checks that the time relations between preceding inspiration minimum

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pressure, the beginning of the actual expiration and the identified maximum pressure thereof correspond to a normal breathing pattern of the patient as established in phase four. If this is the case, the processor sends a signal to the valve system 65 after a period defined during phase four, said valve system passing an evacuation flow which is evacuated through the catheter 52, the artificial nose 55, the conduit 57, the flow-meter 63, the valve system 65 and out through the conduit 67. The rate of the evacuation flow is compared according to known servo feedback principles with the flow corresponding to the flow required in order that the evacuation volume determined during phase four, will be evacuated during the determined period. Deviations, if any, will be corrected by connection or disconnection of valves connected in parallel in the valve system 65. In the way described, during the latter part of the expiration, a flow will be evacuated from the airway from the point where the catheter 52 opens. When the flow of gas from the lungs during the expiration decreases and approaches zero, it will at some time fall below the flow of gas which is evacuated through the catheter 52. Then, gas will flow from the opening of the airway, which could be the nose or the mouth depending on the way in which the patient is breathing, down into the airway towards the opening of the catheter 52. The airway will thus be filled from the top thereof with fresh breathing gas during the latter part of the expiration as a consequence of gas from dead space being evacuated from the airway. It should be noted here that a favourable effect of evacuation of used gas exists until during the inspiration the interface between used gas and fresh gas has passed the opening of the catheter 52, as far as all used gas above said opening has not already been evacuated during the expiration.

The function during the fifth therapeutic phase can be varied in accordance with the therapeutic programme,

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which has been determined during phase four. When a certain volume of gas has been evacuated during part of the final phase of the expiration, the valves in the system 65 will close in accordance with a programme. The control system then checks that a super atmospheric or athmospheric pressure exists in the airway indicating that the inspiration has not started so far, by reading the signal from the pressure sensor 54 which is very quick. During the last part of the expiration pulses of gas are supplied according to the regim established during phase four by the control system 71 giving signals through the conduit 75, which lead to opening of valves in the system 66 under further control of a feedback servosystem, such that the flow, which is measured by the flowmeter 64, corresponds to the determined flow. Alternating with the flow pulses, thus obtained, an evacuation of corresponding volumes of gas takes place by the control system causing valves in the system 65 to open. By this procedure additional volumes of used gas can be flushed from the airway during the final phase of the expiration.

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It is common practice that a catheter 52 of the type shown in FIG 2 is used by patients having respiratory insufficiency, and that catheters which are inserted through the natural airway are used. The purposes of these catheters is to supply to the patient other breathing gases than air, usually oxygen. The device according to FIG 2 in this respect offers considerable advantages as compared with previously known systems for gas supply. It recovers heat and moist from the evacuated gas and returns such heat and moist to the gas which is then supplied to the patient. This makes complicated devices for heating and damping of supplied gases unnecessary. An economically very great advantage is offered by the construction due to the fact that the gas supply can be controlled in such a way that it occurs only during an early part of the inspiration, the

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gas supplied typically oxygen in its entirety will be supplied to the alveolar space to increase the oxygenization of the blood. This advantage can be utilized without affecting the above described functions by extra supply of oxygen through the conduit 58. After evacuation and flushing of the airway during the therapeutic fifth phase above, the pressure in the airway is read by the pressure sensor 54. When the pressure has fallen to subatmospheric level, which means that an inspiration has begun, the control unit 71 supplies signals through the conduit 81, which results in opening of valves in the valve system 78 during extended servo control, such that the intended flow of gas will be supplied to the patient during the intended period which suitably is limited to the initial part of the inspiration so that all of the total gas volume supplied without doubt will reach the alveolar space during the inspiration. Then, the control system returns to the task of identifying the following expiration according to the description above.

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The device according to FIG 2 has several builtin safety systems. Control of the function of the conduit system comprises measurement of the pressures in the three points where the pressure sensors 54, 61 and 62 are located. The pressure differences are related to the flows measured simultaneously, which admits calculation of the resistance of the catheter 52, the artificial nose 55, and the conduits 57 and 58. These resistances are compared in the control unit 71 with earlier estimated recommended values. At deviation from limit values based thereon the function of the device is interrupted and a warning signal is given. An additional safety test is made in connection with the instantaneous interruption of the flow in the conduit 57 and 58, respectively. The interruption should correspond to a corresponding step response in the pressure measured by the quick pressure sensor 54. If this response

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is not the expected one, the catheter may have been dislocated and the function of the device will be interrupted. An important safety function is to stop the evacuation of gas if the patient has closed the airway above the point from where gas is evacuated. This causes an abnormally low pressure to be registered by the pressure sensor 62.

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#### CLAIMS

- 1. Method for reduction of rebreathing of gas from the dead space, c h a r a c t e r i z e d in that, during at least the final phase of the expiration, a flow of used breathing gas is evacuated through a gas conduit which is inserted into the airway.
- 2. Method according to claim 1, c h a r a c t e r iz e d in that the flow rate of used breathing gas which is being evacuated is larger than the flow rate of breathing gas that leaves the respiratory system during the final phase of expiration.
- 3. Method according to claim 1 or 2, c h a r a c te r i z e d in that the evacuation of breathing gas is initiated at a predetermined flow of expiration gas.
  - 4. Method according to any of claims 1 3, c h a rac t e r i z e d in that during at least the final phase of the expiration, a flow of gas is supplied to the airway.
  - 5. Method according to claim 4, c h a r a c t e r i-z e d in that the supply of gas is achieved by a separate gas conduit inserted into the airway.
  - 6. Method according to claim 5, c h a r a c t e r i-z e d in that the evacuation of breathing gas and the supply of gas occurs substantially simultaneously.
  - 7. Method according to claim 4, c h a r a c t e r i-z e d in that the evacuation of breathing gas and the supply of gas occurs alternatingly through one and same gas conduit.
- 8. Method according to claim 6 and 7, c h a r a c ter i z e d in that the evacuated and supplied gas volumes are controlled in order to be in a predetermined mutual relationship.
  - 9. Method according to any of claims 4 8, c h a r-

a c t e r i z e d in that the flow of supplied gas is heated and moistened.

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- 10. Method according to claim 9, c h a r a c t e r-i z e d in that the heat and moisture which have been delivered by expiration gas, is supplied to the flow of supplied gas.
- 11. Method according to claim 10, c h a r a c t e r-i z e d in that heat and moisture are taken from the evacuated flow of used breathing gas.
- 12. Device for reduction of rebreathing of gas from dead space, c h a r a c t e r i z e d by a conduit for insertion into the airway, means connected to the tube for providing an underpressure in the conduit, means for determining a final phase of the expiration of the patient to be treated, and means for initiating underpressure in the conduit in dependence of such a determination.
- 13. Device according to claim 12 in combination with a respirator, c h a r a c t e r i z e d in that said means for determining a final phase of the expiration comprises means for measuring the expiration flow in the respirator and comparing this flow with a predetermined value.
- 14. Device according to claim 13, c h a r a c t e ri z e d in that the conduit is connected to or constructed as a separate passage in a tracheal tube connected to the respirator for supply and discharge of breathing gas.
- 15. Device according to claim 13, c h a r a c t e r-i z e d in that means are provided for supply of gas to the tracheal tube during the expiration phase of the respirator.
- 16. Device according to claim 12, c h a r a c t e ri z e d in that said means for determining a final phase of the expiration comprises a pressure sensor provided on the conduit.
  - 17. Device according to claim 12, c h a r a c t e r-

i z e d in that the conduit is provided with a branching for connection through stop valves to an evacuation device and to a device supplying gas, respectively.

- 18. Device according to claim 17, c h a r a c t e ri z e d in that the tube is provided with an artificial nose.
  - 19. Device according to claim 17 or 18, c h a r a c-t e r i z e d in that means are provided for alternating adjustment of the valves to open position.

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#### AMENDED CLAIMS

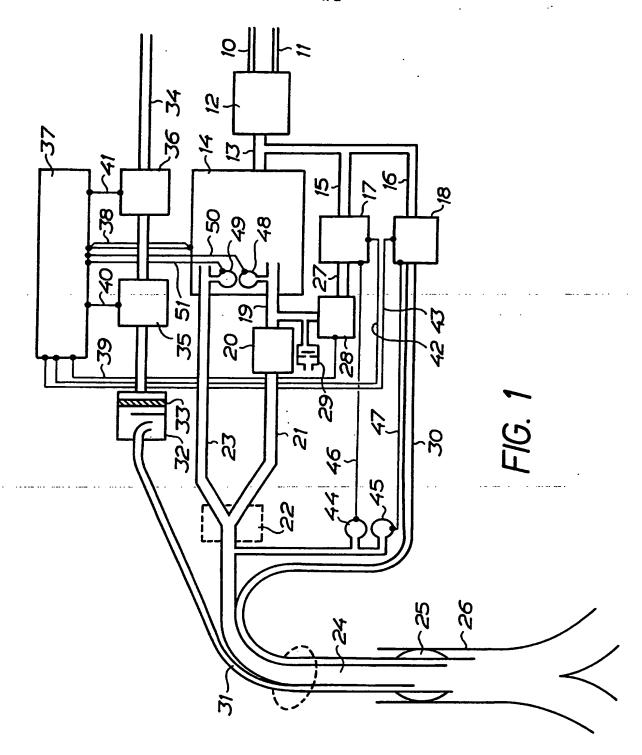
[received by the International Bureau on 15 November 1991 (15.11.91); original claims 1-19 replaced by amended claims 1-13 (2 pages)]

- 1. Method for reduction of rebreathing of gas from
  the dead space, c h a r a c t e r i z e d in that during at
  least the final phase of the expiration, a flow of used
  breathing gas is evacuated through a gas conduit which is
  inserted into the airway, the flow rate of used breathing
  gas which is being evacuated being larger than the flow
  rate of breathing gas that leaves the respiratory system
  during the final phase of expiration, and that
  substantially simultaneously a flow of gas is supplied to
  the airway through a separate gas conduit inserted into the
  airway.
  - 2. Method according to claim 1, c h a r a c t e r-i z e d in that the evacuation of breathing gas is initiated at a predetermined flow of expiration gas.
  - 3. Method according to claim 2, c h a r a c t e r iz e d in that the evacuation of breathing gas and the supply of gas occurs alternatingly through one and same gas conduit.
    - 4. Method according to claim 3, c h a r a c t e r-i z e d in that the evacuated and supplied gas volumes are controlled in order to be in a predetermined mutual relationship.
    - 5. Method according to any of claims 2 4, c h a rac t e r i z e d in that the flow of supplied gas is heated and moistened.
  - 6. Method according to claim 5, c h a r a c t e ri z e d in that the heat and moisture, which have been delivered by expiration gas, is supplied to the flow of supplied gas.
- 7. Method according to claim 6, c h a r a c t e r i-35 z e d in that heat and moisture are taken from the evacuated flow of used breathing gas.

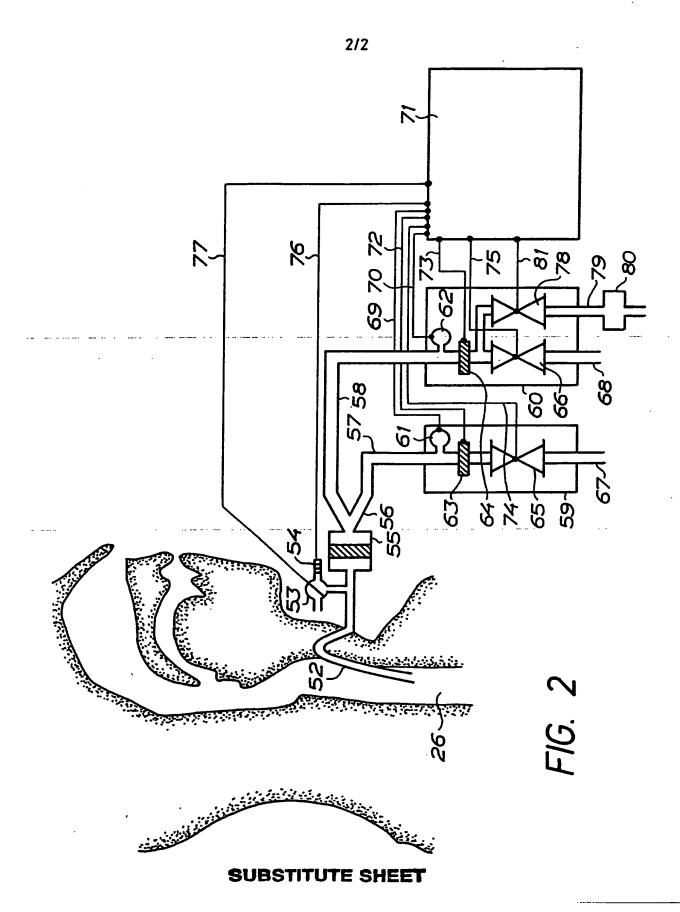
- 8. Device for reduction of rebreathing of gas from dead space, in combination with a respirator, c h a racterized in zed by a conduit for insertion into the airway, which is connected to or constructed as a separate passage in a tracheal tube connected to the respirator for supply and discharge of breathing gas, means connected to the conduit for providing an underpressure in the conduit, means for determining final phase of the expiration of the patient to be treated, and means for initiating underpressure in the conduit in dependence of such a determination, and means for supply of gas to the tracheal tube during the expiration phase of the respirator.
- 9. Device according to claim 8, c h a r a c t e r iz e d in that said means for determining a final phase of
  the expiration comprises means for measuring the expiration
  flow in the respirator and comparing this flow with a
  predetermined value.
- 10. Device according to claim 9, c h a r a c t e ri z e d in that said means for determining a final phase of
  the expiration comprises a pressure sensor provided on the
  conduit.
  - 11. Device according to claim 10, c h a r a c t e r-i z e d in that the conduit is provided with a branching for connection through stop valves to an evacuation device and to a device supplying gas, respectively.
  - 12. Device according to claim 11, c h a r a c t e r-i z e d in that the conduit is provided with an artificial nose.
- 13. Device according to claim 12, c h a r a c t e r-30 i z e d in that means are provided for alternating adjustment of the valves to open position.

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## **SUBSTITUTE SHEET**



#### INTERNATIONAL SEARCH REPORT

International Application No PCT/SE 91/00435

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) <sup>6</sup>							
		tional Patent Classification (IPC) or to both 16/04, 16/10	National Classification and IPC				
II. FIELD	S SEARCH	ED					
. Minimum Documentation Searched <sup>7</sup>							
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IPC5							
		Documentation Searched other to the Extent that such Documen	er than Minimum Documentation ats are included in Fields Searched <sup>8</sup>				
SE,DK,F	I,NO c	lasses as above					
III. DOCUI	MENTS CC	PASIDERED TO BE RELEVANT9					
Category *	Citati	on of Document, <sup>11</sup> with Indication, where ap	propriate, of the relevant passages 12	Relevant to Claim No.13			
Х	DE, C2 2	1-3,6-9, 12-14, 17-19					
	Derwen publ. (MINSK	1,5,6, 12,14					
A	US, A, 5	1,5,12, 13,16					
A	US, A, se	1,5, 12					
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* Special "A" docu cons "E" earlii filing "L" docu whic citati "O" docu other "P" docu later	the international filing date ct with the application but a or theory underlying the e, the claimed invention annot be considered to e, the claimed invention an inventive step when the or more other such docupations to a person skilled patent family						
IV. CERTIF		niction of the international Search	Date of Mailing of this International Se	earch Report			
9th September 1991  Date of the Actual Completion of the International Search  1991 -09- 18							
International	<i>!</i>						
SWEDISH PATENT OFFICE Leif Karnsater							

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# ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.PCT/SE 91/00435

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the Swedish Patent Office EDP file on 91-07-31. The Swedish Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

	Patent document ted in search report	Publication date		family ber(s)	Publication date
DE-C2-	3204110	84-08-02	FR-A-B- US-A-	2521013 4565194	83-08-12 86-01-21
US-A-	4265237	81 <b>-</b> 05-05	CH-A-B- DE-A- FR-A- GB-A-B- SE-A-	649714 2831313 2431292 2025240 7906135	85-06-14 80-02-07 80-02-15 80-01-23 80-01-18
US-A-	4270530	81-06-02	AT-B- CH-A- DE-A-C- FR-A-B- GB-A-B- SE-B-C- SE-A-	382316 643461 2847681 2440743 2033759 430848 7909072	87-02-10 84-06-15 80-05-08 80-06-06 80-05-29 83-12-19 80-05-04
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